

SAFETY DATA SHEET
 according to Regulation (EC) No. 453/2010
 Dental Use



Date Issued : 10/04/2011
SDS No : 226-001.3
Date Revised : 07/08/2015
Revision No : 2

Lumaloc™ Vinyl Polysiloxane

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : 19035
Product name : Lumaloc™ Vinyl Polysiloxane
Product description : Dental Impression Material

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Orthodontic Indirect Bonding System, Part 1 of 2

1.3. Details of the supplier of the safety data sheet

Manufacturer

Opal® Orthodontics
 505 W 10200 S
 South Jordan, UT 84095

Distributor

MPG Service GmbH
 Gereonstrasse 34-36
 D-50670 Cologne, Germany
 Email: mpgservicekoeln@googlemail.com
Emergency Phone : +49(0)2203-35-92-0

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA) :(800) 424 - 9300
(INTERNATIONAL) :+1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 1999/45/EC

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.
 This material is not considered hazardous to health.

Classification according to Regulation (EC) No 1272/2008 [CLP]

Health : Eye Irritation

2.2. Label elements

Classification according to Directive 1999/45/EC : This material is not considered to be hazardous for the health.

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictogram(s) :



Exclamation
 mark

Signal Word : DANGER

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Hazard statement(s)	: H319: Causes serious eye irritation.
Precautionary statement(s)	
Prevention	: P314: Get medical advice/attention if you feel unwell.
Response	: P305: IF IN EYES: P351: Rinse cautiously with water for several minutes. P337+P313: If eye irritation persists: Get medical advice/attention. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P332+P313: If skin irritation occurs: Get medical advice/attention.
Storage	: P273: Avoid release to the environment.
Disposal	: P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-10/11/2003)

2.3. Other hazards

Immediate concerns : None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Quartz, Silicon Dioxide	14808-60-7	238-878-4	< 60	R45	Not classified
Tridecyl Alcohol Ethoxylated	24938-91-8	N/A	< 5	R51	EYE DMG.,Cat. 1; H318
Silicones and Siloxanes, dimethylsiloxane	83148-62-9	N/A	< 50	N/A	Not classified

For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes	: Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.
Following skin	: No special measures required.
Following ingestion	: No special measures required.
Following inhalation	: No special measures required.

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4.2. Most important symptoms and effects, both acute and delayed

Eyes : May cause eye irritation.
Skin : None expected for this product.
Ingestion : None expected for this product.
Inhalation : None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed

Notes to physician : Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : None known.
Explosion hazards : Not Determined
Fire explosion : Not Determined
Sensitive to static discharge : Not Determined
Sensitivity to impact : Not Determined

5.3. Advice for firefighters

Fire fighting procedures : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
Fire fighting equipment : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO₂)

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

Water spill : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

Small spill : Vacuum or sweep up material and place in a disposal container.
Large spill : Shovel or vacuum spill and place in a container for disposal.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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Handling : No special measures required.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Orthodontic Indirect Bonding System, Part 1 of 2.

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection

Skin protection : Wear suitable gloves.

Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance : Paste

Colour : Translucent

Odour : Odorless or no characteristic odor

Solubility in water : Not miscible or difficult to mix.

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Not Determined

10.5. Incompatible materials

Incompatible materials : Not Determined

10.6. Hazardous decomposition products

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Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : Not Determined
Oral LD₅₀ : Not Determined
Inhalation LC₅₀ : Not Determined

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.
96-hour LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined
96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not Determined

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

12.6. Other adverse effects

Environmental data : Do not allow undiluted product or large quantities to reach ground water, water ways or sewage system.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

SECTION 14: Transport information

14.1. UN number

UN number : N/A

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14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : Not Dangerous Goods

RID - rail : Not Dangerous Goods

IMDG - sea : Not Dangerous Goods

IATA - air : Not Dangerous Goods

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : Not Determined

Additional information : Quartz is listed by IARC, NTP, or OSHA as a carcinogen.
 This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R45: May cause cancer.
 R51: Toxic to aquatic organisms.
 EYE DMG., Cat. 1: Eye Damage, Category 1
 H318: Causes serious eye damage.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 04/04/2013 SDS. Revised: **Section 1:** GENERAL USE, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 4:** INGESTION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INGESTION, INHALATION, SKIN). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, WATER SPILL, . **Section 7:** SHELF LIFE, STORAGE, . **Section 8:**

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PERSONAL PROTECTIVE EQUIPMENT - EYES AND FACE . **Section 9:** PERCENT VOLATILE. **Section 10:** CONDITIONS TO AVOID, HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABILITY, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat)). **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 13:** DISPOSAL METHOD. **Section 14:** ROAD AND RAIL (ADR/RID) (ROAD AND RAIL (ADR/RID), MARINE POLLUTANT #1), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, RoHS, SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

General statements

Manufacturer disclaimer

: N/A= Not Applicable

: FOR ORTHO USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.